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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,110	04/01/2004	Huwei Tan	0010.0010US1	8501

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EXAMINER	
FERNANDEZ, KATHERINE L	

ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,110	TAN, HUWEI	
	Examiner	Art Unit	
	KATHERINE L. FERNANDEZ	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claim 1-7, 9-11,13-18,20-22,28-45,47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moreno et al. (US Pub No. 2001/0047137) in view of Tan et al. ("Multivariate calibration of spectral data using dual-domain regression analysis", 2003) as cited by applicant.

Moreno et al. disclose a method and system for optically analyzing blood vessel walls, their invention comprising: receiving optical signals from the vessel walls with a detector system; resolving a spectrum of the optical signals to generate spectral data with a spectrometer and using the spectral data to analyze the vessel walls with an analyzer (see Abstract; pg. 4, paragraph [0013]; pg. 8, paragraph [0051]; pg. 10, paragraph [0072]-[0076]; pg. 12, paragraphs [0084]-[0087]). The blood vessel walls are illuminated with an optical source and generates near infrared light (pg. 4, paragraph [0013]; pg. 10, paragraph [0072], [0075]). The step of receiving the optical signals comprises detecting returning radiation to a catheter head (see Abstract; pg. 4, paragraph [0013]; pg. 8, paragraph [0051]; pg. 10, paragraph [0072]-[0076]; pg. 12, paragraphs [0084]-[0087]). Moreno et al. further disclose that the spectral data is used to determine whether the blood vessel walls are comprised of vulnerable or non-vulnerable plaque (see Abstract; pg. 4, paragraph [0013]; pg. 8, paragraph [0051]; pg.

10, paragraph [0072]-[0076]; pg. 12, paragraphs [0084]-[0087]). They further disclose that the spectral data underwent preprocessing (pg. 10, paragraph [0075]).

However, Moreno et al. do not disclose that their method involves transforming the spectral data into dual-domain spectral data. Further, they do not specifically disclose the limitations of instant claims 2-3, 9, 10-11, 13-18, 29-30,36-38 and 40-45.

Tan et al. disclose the use of dual-domain regression analysis applied to spectral data (pg. 292, column 1, 2nd paragraph; pg. 292-295, Section 2). The dual-domain regression analysis comprises applying a wavelet prism (pg. 292, column 2, Section 2, 1st paragraph). Further, the step of transforming the spectral data into the dual-domain spectral data comprises applying a time-frequency transform and decomposition methods, optimized in response to analytes and interferants (pg. 292, column 2, 1st paragraph; pg. 297, column 1, 2nd paragraph; pg. 298, column 2, 2nd paragraph). Their discrimination model is a single domain model and a dual domain model (pg. 292, Section 2.1; pg. 296, right column). Tan et al. disclose that aspects of the spectra, such as low-frequency components and noise, can be stripped out in some situations to reduce the complexity of multi-variate regression models (pg. 292, column 2, 2nd paragraph). Before transforming the spectral data into the dual domain spectral data, Tan et al. disclose that the NIR spectra of the samples are mean-centered (i.e. a preprocessing step is performed before transforming the spectral data into the dual domain spectral data) (pg. 292, column 2, 1st paragraph). Further, they disclose that they perform dual-domain multivariate regression techniques to analyze the data (pg. 293-295, Section 2.2). The regression technique comprises applying a weight strategy

(pg. 294, column 1, 3rd paragraph through column 2, 3rd paragraph, referring to the use of a weighted average regression vector). Cross-validation techniques are applied in the step of applying a weight strategy (pg. 294, column 1, 3rd paragraph through column 2, 1st paragraph). At the time of the invention, it would have been obvious to one of ordinary skill in the art to transform the spectral data into dual-domain spectral data in the method of Moreno et al, as taught by Tan et al., as dual-domain spectral analysis has been shown to have improvements in prediction power, robustness, and model complexity (pg. 301, Section 5).

3. Claims 8, 24 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moreno et al. in view of Tan et al. as applied to claims 1 and 28 above, and further in view of Carr (US Pub No. 2004/0243004).

As discussed above, the above combined references meet the limitations of claim 1. However, they do not specifically disclose that the step of using dual-domain spectral data to analyze the vessel wall comprises measuring vulnerability for a risk of heart attack. Carr discloses a minimally invasive technique for detecting vulnerable plaques (pg. 1, paragraph [0001]). They disclose that coronary disease can be caused by vulnerable plaques which are engrained or embedded in the arterial wall (pg. 1, paragraphs [0003]-[0004]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to have their step of analyzing the vessel walls comprise measuring vulnerability for a risk of heart attack, as Carr teaches that coronary disease can be caused by vulnerable

plaques which are engrained or embedded in the arterial wall (pg. 1, paragraph [0003]-[0004]).

4. Claims 19, 23, 25, 46, 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moreno et al. in view of Tan et al. as applied to claims 1 and 28 above, and further in view of Braun et al. (US Patent No. 6,321,164).

As discussed above, the above combined references meet the limitations of claims 1 and 28. However, they do not specifically disclose that their analysis further comprises applying a receiver operating characteristic-area under curve analysis, and that such an analysis can be used to set a decision boundary. Braun et al. disclose a method and apparatus for predicting the presence of at least one congenital or acquired imbalance or therapeutic condition from at least one time-dependent measurement profile (column 3, lines 29-32). They disclose a classification process that includes using an ROC curve to determine true-positive and false-positive proportions at different "decision boundaries" for the diagnostic test (column 13, lines 1-49). They disclose that the area under the curve is equivalent to an estimate of the probability that a randomly chosen positive specimen will have a more positive result than a randomly chosen negative specimen (column 13, lines 1-49). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to have their analysis further comprise applying a receiver operating characteristic-area under curve analysis, and that such an analysis be used to set a decision boundary, as their invention requires a separation/classification of data

and Braun et al. disclose that an ROC curve can be used to separate and classify data (column 13, lines 1-49).

5. Claims 26 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moreno et al. in view of Tan et al. as applied to claims 1 and 28 above, and further in view of Zelenchuk (US Patent No. 6,768,918).

As discussed above, the above combined references meet the limitations of claims 1 and 28. However, they do not specifically disclose that their analysis comprises applying a Mahalanobis classifier. Zelenchuk disclose a system and method for the discrimination of healthy and diseased tissue (lines 55-61). They disclose that this can be done by classifying or comparing normalized intensities into one or more groups, which can be done by using a Mahalanobis-based classifier which is computationally efficient (column 2, lines 1-18, lines 44-61). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to have their analysis comprise applying a Mahalanobis classifier, as taught by Zelenchuk, as this is a known method of separating/classifying data and is computationally efficient (column 2, lines 1-18).

6. Claims 27 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moreno et al. in view of Tan et al. and Zelenchuk as applied to claims 26 and 52 above, and further in view of Braun et al.

As discussed above, the above combined references meet the limitations of claims 26 and 52. However, they do not specifically disclose that the classifier comprises applying a receiver operating characteristic-area under curve analysis

technique to set decision boundary (surface) in high dimension space. Braun et al. disclose a method and apparatus for predicting the presence of at least one congenital or acquired imbalance or therapeutic condition from at least one time-dependent measurement profile (column 3, lines 29-32). They disclose a classification process that includes using an ROC curve to determine true-positive and false-positive proportions at different "decision boundaries" for the diagnostic test (column 13, lines 1-49). They disclose that the area under the curve is equivalent to an estimate of the probability that a randomly chosen positive specimen will have a more positive result than a randomly chosen negative specimen (column 13, lines 1-49). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to have their classifier comprise applying a receiver operating characteristic-area under curve analysis technique to set a decision boundary, as their invention requires a separation/classification of data and Braun et al. disclose that an ROC curve can be used to define a decision boundary (column 13, lines 1-49).

Response to Arguments

7. Applicant's arguments with respect to claims 1-53 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768